UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

JOYCE BAAR Plaintiff, v. ZIMMER US, INC.; ZIMMER-BIOMET HOLDINGS, INC.; ZIMMER, INC.; AND ZIMMER SURGICAL, INC. Defendants.	)	CIVIL ACTION NO.: 3:19-cv-00363 COMPLAINT & DEMAND FOR JURY TRIAL

Plaintiff, Joyce Baar, by and through her attorneys, respectfully submits the following Complaint and Jury Demand against Defendants Zimmer US, Inc.; Zimmer Biomet Holdings, Inc.; Zimmer, Inc.; and Zimmer Surgical, Inc. (collectively referred to as "Zimmer" or "Defendants"), and alleges the following:

INTRODUCTION

1. This product liability action relates to the design, development, manufacture, testing, marketing, promotion, distribution, and sale of Zimmer's defective hip implant components known as the Zimmer VerSys Hip System Collared Beaded MidCoat Femoral Stem ("Collared Beaded Midcoat"), the Zimmer VerSys Hip System Femoral Head ("VerSys"), the Zimmer Continuum Cluster-Hole Acetabular System Shell, and the Zimmer Trilogy Acetabular System Longevity Crosslinked Polyethylene Liner (collectively referred to as the "Devices" or "VerSys Hip System").

2. Zimmer designs, develops, manufactures, markets, tests, distributes and sells reconstructive orthopedic implants, including joint, dental and spinal implants, trauma products and related orthopedic surgical products. Zimmer's related orthopedic surgical products include surgical supplies and instruments designed to aid in orthopedic surgical procedures.

3. The VerSys Hip System is an orthopedic device used in total hip replacement surgery.

4. On May 2, 2012, the following Zimmer hip components were surgically implanted into Plaintiff Joyce Baar's right hip:

- VerSys Hip System Femoral Head, 12/14 Taper, 36mm, Ref 00-8018-036-01;
- VerSys Hip System Collared Beaded Midcoat Collared Femoral Stem, 12/14 Neck Taper, Extended Neck Offset, Size 11 Extended Body, Ref 00-7840-011-20;
- Continuum Cluster-Hole Acetabular System Shell, 52mm, Ref 00-8757-052-01; and
- Trilogy Acetabular System Longevity Crosslinked Polyethylene Liner, Standard, 36mm ID, Ref 98-0001-200-11.

5. Plaintiff Baar subsequently developed trunnionosis, adverse local tissue reaction, and other complications in her right hip requiring revision surgery on July 26, 2017.

6. The United States Food and Drug Administration's ("FDA") Manufacturer and User Facility Device Experience ("MAUDE") database for adverse events details numerous complaints of premature device failure for the same or similar modular VerSys hip systems, for reasons similar to the failures experienced by Ms. Baar. For example, on May 17, 2018, an adverse event report was filed involving a failed femoral head nearly identical to the femoral head used in Ms. Baar's initial surgery.[1] On June 6, 2018, another report was filed by a physician

[1] See FDA MAUDE Database, Report Key 7525521, available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=7525521&pc=LZO.

involving the VerSys femoral head and lists hairs found in the packaging of the devices.[2] A third adverse event reported on June 14, 2018 is connected to the July 11, 2014, failure of a patient's VerSys system due to corrosion, trunnionosis, blackened tissue and elevated metal ion levels.[3]

7. Many of these and other recent reports were only sent to FDA years after the injuries occurred, and they were reported by patients, physicians, or lawyers, not by Zimmer or its sales representatives.

8. There are more than five hundred (500) adverse event reports related to the VerSys system in the FDA's database between June 2010 and June 2018. Furthermore, there are lawsuits with similar allegations involving the VerSys hip system pending in other federal courts, including in Pennsylvania, Missouri, Maryland, Tennessee, Washington, and elsewhere.

9. The Devices implanted into Plaintiff's right hip were defective and have caused her to suffer significant physical and emotional pain, subsequent surgery, extensive medical expenses, impairment of her daily routines, and restrictions from engaging in normal physical activities.

10. At all relevant times, Zimmer knew or should have known that the Devices were defective and not fit for the patients in whom they were implanted.

11. On or about January 28, 2003, a similar component to Plaintiff's hip system, the modular VerSys Hip System Fiber Metal Midcoat Femoral Stem, became the subject of a Class II recall by the FDA because the femoral heads would "not seat onto the taper of the hip stem[.]"[4]

[2] *See* FDA MAUDE Database, Report Key 7491140.
[3] *See* FDA MAUDE Database, Report Key 7604925.
[4] See https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?id=25698.

12. The use of modular hip systems such as the VerSys hip system has been discontinued by many manufacturers or it has been the subject of recalls by manufacturers due to unreasonably high revision rates. These high failure rates are due to mechanical failures, dissociation of modular components, corrosion, and metal ion release. See Jung Taek Kim, et. al., *Implant Design in Cementless Arthroplasty*, Hip & Pelvis 65-75 (June 2016)(citing, inter alia, "… galvanic corrosion due to different metals contacting the modular junction, pitting corrosion by micromotion, and crevice corrosion are believed to contribute to complications to different extents.").

PARTIES

13. Plaintiff Joyce Baar (hereafter as "Ms. Baar" or "Plaintiff") is over the age of 18 and is a citizen and resident of Highland Springs (Henrico County), Virginia.

14. Defendant Zimmer US, Inc. is a Delaware corporation with its principal place of business at 345 East Main Street, Warsaw, Indiana, 46580-2746. At all times relevant to this action, Zimmer US, Inc. was a wholly owned subsidiary of Zimmer, Inc. At all times relevant to this action, Zimmer US, Inc. tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the VerSys Hip System in interstate commerce and throughout the Commonwealth of Virginia and generated substantial revenue as a result.

15. Defendant Zimmer Biomet Holdings, Inc. formerly known as Zimmer Holdings, Inc., is a Delaware corporation with its principal place of business at 345 East Main Street, Warsaw, Indiana, 46580-2746. At all times relevant to this action, Zimmer Biomet Holdings, Inc. was the publicly traded holding company with wholly owned subsidiaries that it controlled which tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged,

promoted, advertised, marketed, distributed, and/or sold the Zimmer VerSys Hip System in interstate commerce and throughout the Commonwealth of Virginia and generated substantial revenue as a result.

16. Defendant Zimmer, Inc. is a Delaware corporation with its principal place of business at 1800 West Center Street, Warsaw, Indiana, 46581-0708. At all times relevant to this action, Zimmer, Inc. was a wholly owned subsidiary of Zimmer Biomet Holdings, Inc. At all times relevant to this action, Zimmer, Inc. tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Zimmer VerSys Hip System in interstate commerce and throughout the Commonwealth of Virginia and generated substantial revenue as a result.

17. Defendant Zimmer Surgical, Inc. is a Delaware corporation with its principal place of business at 200 West Ohio Avenue, Dover, Ohio 44622-9642. At all times relevant to this action, Zimmer Surgical, Inc. was a wholly owned subsidiary of Zimmer Biomet Holdings, Inc. At all times relevant to this action, Zimmer Surgical, Inc. tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Zimmer VerSys Hip System in interstate commerce and throughout the Commonwealth of Virginia and generated substantial revenue as a result.

18. At all relevant times, each of the Defendants and their directors and officers acted within the scope of their authority of each Defendant and on behalf of each other Defendant.

19. At all relevant times, Defendants possessed a unity of interest between themselves and Zimmer exercised control over its subsidiaries and affiliates. As such, each Defendant is individually, as well as jointly and severally, liable to Ms. Baar for her injuries, losses and damages.

JURISDICTION AND VENUE

20. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1332(a) because the Plaintiffs and Defendants are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

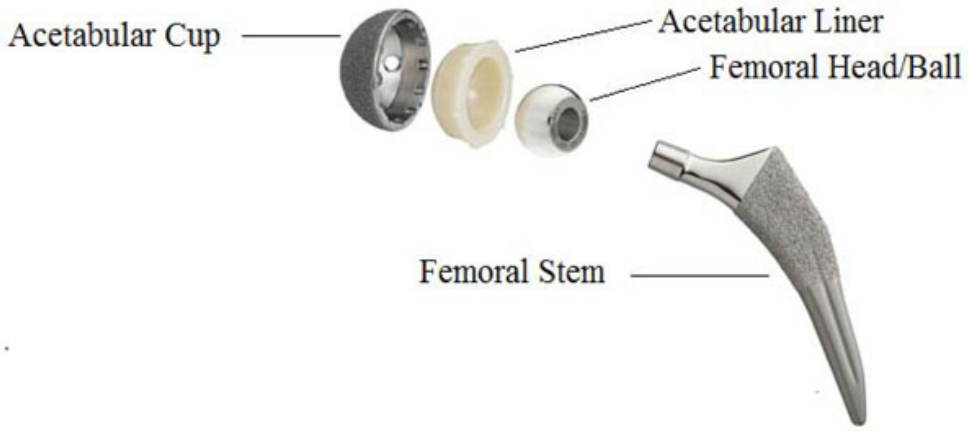
21. Defendants are subject to the personal jurisdiction of this Court, and venue is therefore proper herein pursuant to 28 U.S.C. § 1391, because Defendants did and do business within and have continuous and systematic contacts with the Commonwealth of Virginia, have consented to jurisdiction in the Commonwealth of Virginia and/or committed a tort in whole or in part in the Commonwealth of Virginia against Plaintiff, as more fully set forth herein. On information and belief, Defendants also advertised in this judicial district, made material omissions and representations in this judicial district, and breached warranties in this judicial district.

FACTUAL ALLEGATIONS

22. The allegations in the preceding paragraphs are incorporated by reference as though fully set forth herein.

23. A patient's natural hip joint connects the thigh (femur) bone of the leg to the pelvis. The hip is characterized as a ball and socket joint. The socket is the cup shaped portion of the acetabulum into which the femoral head (ball) at the top of the femur bone inserts and articulates. Both the femoral head and acetabular socket are covered with cartilage forming a natural surface upon which the parts may move freely. The primary function of the hip joint is to support the weight of the body in both static (i.e. standing) and dynamic (i.e. walking or running) postures.

24. In some patients, cartilage can become damaged due to trauma, disease, or aging (arthritis). When this occurs, a hip replacement may be indicated. A total hip replacement device typically consists of four separate components: (1) a femoral stem, (2) a femoral head/ball, (3) an acetabular liner, and (4) an acetabular cup/shell as demonstrated below.



25. These four components are manufactured from metal alloys, plastic or ceramic materials and are surgically implanted to replace a patient's damaged or diseased natural anatomy.

26. A total hip arthroplasty surgical procedure requires removing the arthritic femoral head and replacing the patient's natural anatomy with a femoral stem upon which a femoral head is impacted. The acetabulum is then reamed to accommodate the acetabular shell into which the liner is then placed. Once all the parts are inserted, the ball articulates within the acetabular liner of the hip implant device, much like the patient's natural hip

27. The VerSys Hip System has what is referred to as head-neck modularity at the junction between the VerSys femoral head and the trunnion on the neck of the Collared Beaded Midcoat femoral stem.

28. The trunnion is the tapered top end of the Collared Beaded Midcoat femoral stem upon which the VerSys femoral head is affixed during hip replacement. The trunnion of the

Collared Beaded Midcoat femoral stem has a taper angle that is wider at the proximal than distal end. The bore (or hollow portion of the inside of the ball) of the VerSys femoral head has a corresponding taper angle which is wider at the distal than proximal end. When the VerSys femoral head is impacted onto the trunnion of Collared Beaded Midcoat femoral stem, the dissimilar angles of the trunnion (the male taper) and the bore of the femoral head (the female taper) form an interference fit. The contact area between the inside of the bore of the femoral head and the trunnion of the femoral stem is called the taper junction or interface. This type of taper junction is known as a Morse taper, which relies on the dissimilar angles at the femoral head-neck interface to obtain fixation.

29. This taper junction is designed to prevent motion when assembled; however, micromotion can develop over time at a malfunctioning taper junction resulting in articulation of the bore of the femoral head against the trunnion of the femoral stem to the degree that the oxide layer existing between the components is gradually worn down resulting in metal debris wearing off the component parts. Fluid from the hip joint can also enter a malfunctioning taper junction facilitating a corrosive process.

30. On or about May 2, 2012, Ms. Baar underwent a surgical procedure at Bon Secours Health System Saint Mary's Hospital in Richmond, Virginia performed by Dr. Fred J. McGlynn, where the Devices were implanted in her right hip joint.

31. Subsequent to being implanted with the Devices in her right hip, Ms. Baar began to experience adverse symptoms including but not limited to elevated metal ion levels and adverse local tissue reaction.

32. Consequently, Ms. Baar underwent a revision and replacement surgery of the Devices implanted in her right hip on July 26, 2017. The surgery was performed by Dr. Jason Hull at Bon Secours Health System Saint Mary's Hospital in Richmond, Virginia.

33. During the procedure, Dr. McGrory found a "ring of definitive darkened material at the head and neck junction consistent with corrosion and/or fretting debris." Dr. McGrory also noted in his operative report that there was "dark-tinged fluid within the taper itself."

34. Dr. McGrory replaced the cobalt-chromium VerSys femoral with a ceramic femoral head thereby removing the metal-on-metal junction in Ms. Baar's hip system.

35. The mechanism of failure in Plaintiff's VerSys Hip System was the same mechanism of failure that Defendants had marketed and warranted would not occur because of the VerSys Hip System's design and composition. It was also the same mechanism of failure that the medical and scientific community had been studying and documenting in modular device designs since the 1990s, and that Zimmer itself studied in wear testing as early as 1996. As noted above, modular devices largely have been abandoned by many manufacturers due to the risk of crevice corrosion, trunnionosis at the stem-neck junction, increased levels of cobalt and chromium ions in patients' bodies, and metallurgical reaction due to the use of dissimilar metals in the femoral stem and femoral head.

36. In reliance on Defendants' marketing of the devices, Ms. Baar and her physicians expected that these Devices would provide her with better stability, function, comfort, and range of motion than other hip replacement devices available on the market. In reliance on Defendants' marketing of the Devices, Ms. Baar and her physician also expected that these Devices should have lasted many more years than she experienced.

37. Had Ms. Baar known that the Devices would cause the injuries that she ultimately suffered, she would not have elected to use them during her hip replacement surgery.

38. Ms. Baar's hip device system was approved by the FDA through the 510(k) process, which refers to Section 510(k) of the Medical Device Amendments of 1976 (hereafter "MDA") of the Federal Food, Drug and Cosmetic Act. Under this process, device manufacturers are only required to notify the FDA at least 90 days before they market a device claimed to be "substantially equivalent" to a device the FDA approved for sale prior to 1976, when the MDA was enacted. No clinical testing is required under this process.

39. Subsequent amendments to the MDA allowed for 510(k) clearance for products deemed "substantially equivalent" to post-MDA, 510(k) cleared devices. Through this domino effect, devices deemed "substantially equivalent" to devices previously deemed "substantially equivalent" to devices approved for sale by the FDA prior to 1976 could be sold to patients in a matter of 90 days without any clinical testing. Clearance for sale under the 510(k) process does not equate to FDA approval of the cleared device.

40. In 2012, at the request of the FDA, the Institute of Medicine of the National Academies (hereafter "IOM") conducted a thorough review of the 510(k) process, coming to the following major conclusions:

> **The 510(k) clearance process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions. The 510(k) process cannot be transformed into a pre-market evaluation of safety and effectiveness so long as the standard for clearance is substantial equivalence to any previously cleared device.**[5]

[5] The Institute of Medicine of the National Academies, *Medical Devices and the Public Health – The FDA 510(k) Clearance Process at 35 Years*,193, *available at* https://www.nap.edu/read/13150/chapter/1

41. The IOM explained, "The assessment of substantial equivalence does not require an independent demonstration that the new device provides a 'reasonable assurance of safety and effectiveness.'" Further, the IOM even pointed out that the classification of predicate devices approved for sale prior to the 1976 MDA "did not include any evaluation of the safety and effectiveness of individual medical devices . . . Thus is common for devices to be cleared through the 510(k) program by being found substantially equivalent to devices that were never individually evaluated for safety and effectiveness, either through the original device classification program or through the 510(k) process."[6]

42. Selection of a femoral head made of cobalt-chromium such as the VerSys rather than a ceramic head to pair with the titanium alloy neck of the VerSys femoral stem significantly increases the risk of toxic amounts of corrosion and fretting debris which causes pain, swelling, metallosis, trunnionosis, tissue necrosis, adverse local tissue reaction, osteolysis, dislocation, and/or the need for early revision surgery.

43. Zimmer's pre-market corrosion and fatigue testing utilizing VerSys modular femoral heads showed thick amounts of debris at both modular junctions and other fretting-induced changes.

44. The Collared Beaded Midcoat femoral stem is made of a titanium alloy, which is a dissimilar metal compared to the cobalt-chrome VerSys femoral head, leading to further metallurgical reactions that generate debris and corrosion.

45. In designing the VerSys Hip System, Zimmer knew that the use of dissimilar metal alloys as well as taper size and geometry, trunnion surface finish, and rigidity contribute to causing fretting and corrosion at the femoral head-femoral stem taper interface.

[6] *Id*. at 4.

46. Zimmer failed to disclose the risk of corrosion and fretting with the Devices.

47. Zimmer used it distributors and sales representatives to communicate with doctors, including Plaintiff's implanting surgeon, Dr. McGlynn, and other physicians at Bon Secours Health System Saint Mary's Hospital.

48. Zimmer and its sales representatives intentionally or negligently failed to accurately describe the risks of fretting and corrosion, release of metal debris and metal ions into the surrounding tissue and the blood associated with the use of the VerSys Hip System.

49. Had Zimmer disclosed the accurate information about this particularly dangerous failure mode, i.e., fretting and corrosion, Plaintiff and her surgeon would not have used the VerSys Hip System.

50. Despite their knowledge of the serious injuries associated with use of these VerSys Hip System, Zimmer engaged in a marketing and advertising program which, as a whole, by affirmative and material misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the use of the VerSys Hip System was safe.

51. At all relevant times, Zimmer knew or should have known that the VerSys Hip System was not safe for the patients in whom it was implanted, including Plaintiff, because of its unacceptable failure rate.

53. As a direct and proximate result of the defective nature of the Devices and the Defendants' wrongful conduct, including but not limited to the lack of clinical testing before the Devices reached the market, Plaintiff sustained and continues to suffer economic damages and severe and permanent injuries, including pain, suffering, and emotional distress. As a result, Plaintiff has sustained and will continue to sustain damages in an amount to be proven at trial, but which will exceed the jurisdictional minimum of this Court.

THE FEDERAL REQUIREMENTS

54. The Medical Device Amendments of 1976 to the Food Device Cosmetic Act established the current regulatory framework for medical devices.

55. The MDA, in theory, requires medical devices like the VerSys Hip System to undergo premarket approval by the FDA, a process which obligates the manufacturer to design and implement a clinical investigation and to submit the results of that investigation to the FDA.

56. Premarket approval is a rigorous process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and when relevant, packing and installation of, such device; samples or device components required by the FDA; and a specimen of the proposed labeling.

57. The FDA may grant premarket approval only if it finds that there is reasonable assurance that the medical device is safe and effective and must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

58. A medical device on the market prior to the effective date of the MDA – a so-called "grandfathered" device – is not required to undergo premarket approval. In addition, a medical device marketed after the MDA's effective date may bypass the rigorous premarket approval process if the device is "substantially equivalent" to a "grandfathered" pre-MDA device (i.e., a device approved prior to May 28, 1976).

59. This exception to premarket approval is known as "510(k) clearance" which only

requires the manufacturer to notify the FDA under section 510(k) of the MDA of its intent to market a device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then "clear" the new device for sale in the United States.

60. 510(k) clearance is distinct from the FDA's pre-market approval ("PMA") process in that clearance does not require clinical confirmation of safety and effectiveness and as such the manufacturer retains all liability for the assertions of safety and effectiveness.

61. All the component parts comprising Plaintiff's VerSys Hip System were cleared for marketing by the FDA pursuant to 510(k) of the MDA or were marketed without receiving either 510(k) clearance or PMA approval by the FDA.

62. According to the U.S. Supreme Court in *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 346 (2001), the Supreme Court explained that demonstrating that a device qualifies for this, known as the "§ 510(k) process," means that: "[s]ection 510(k) submissions must include the following: 'Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use,' 21 CFR § 807.87(e) (2000); and must include "[a] statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement," § 807.87(f); "[a] statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted," § 807.87(k); and "any additional information regarding the device requested by the [FDA] Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution," § 807.87(l).

63. The FDCA requires cleared medical devices to be demonstrated to be safe and effective for each intended use.[7] Not only is the medical device itself part of the 510(k) process, but so is the labeling and packaging that comes with it.

64. A manufacturer is required to give adequate directions for the use of a medical device such that a "layman can use a device safely and for the purposes for which it is intended"[8], and conform to section 801.15 requirements governing the appearance of the label.

65. The FDCA requires medical device manufacturers to disclose all material facts in advertising and labeling.[9] False and misleading labeling is considered misbranding[10], which is prohibited.[11]

66. The distribution of a "misbranded" medical device is prohibited pursuant to 21 U.S.C. §§ 331(a), (k) (2012) and 21 U.S.C. § 352(f) (2012).

67. The FDCA provides that a medical device is misbranded if, among other things, the labeling did not contain adequate directions for use, which includes critical information about adverse events. Adequate directions for use cannot be written including adverse events when the manufacturer has failed to disclose those adverse events to the FDA. Therefore, the labeling becomes inadequate and the product is misbranded.

68. Federal law requires a manufacturer to ensure that any warranty statements it voluntary makes are truthful, accurate, not misleading, and consistent with applicable federal and state law.[12]

[7] 21 U.S.C. § 360e(c)(2)(A)(iv) (2012).
[8] 21 C.F.R. § 810.5 (2012).
[9] 21 U.S.C. § 321(n) (2012).
[10] 21 U.S.C. § 321(a), q(1) (2012).
[11] 21 U.S.C. § 331(b).
[12] 21 U.S.C. § 331(b) (effective 2013).

69. Under the FDCA, medical device manufacturers are prohibited from introducing the adulteration or misbranding of any medical device into interstate commerce.[13]

A. The FDA, By Its Regulations and 510(k) Clearance Process, Prohibits Misleading or False Promotional and Marketing Activities

70. The FDA regulates the manufacture, sale, and distribution of medical devices in the United States under the authority of the FDCA. This authority includes oversight of labeling and advertising for all medical devices.[14]

71. Under the FDCA and FDA's implementing regulations, labeling, promotional advertisements, and making claims about medical devices are deemed misleading if they omit or ignore certain information about the product's risks

72. A medical device shall be deemed to be misbranded if its labeling is false or misleading in any particular. Labeling or advertising may be considered misleading if it fails to reveal material facts about the product being promoted, including facts about the consequences that can result from use of the product as suggested in a promotional piece.[15]

B. After a Medical Device is Cleared via the 510(k) Process, a Device Manufacturer Still Has Requirements, Including General Reporting Requirements, to the FDA Mandated by Federal Regulations

73. A manufacturer's obligations do not end with 510(k) clearance by the FDA. Even after clearance, manufacturers are required to report to the FDA "no later than 30 calendar days after the day: the manufacturer receive[s] or otherwise become[s] aware of information, from any source, that reasonably suggests that a device" marketed by the manufacturer:

a. May have caused or contributed to death or serious injury; or

b. Has malfunctioned and this device or a similar device [likewise marketed

[13] *Id.*
[14] See 21 U.S.C. § 352(a), (n), (q) & (4) (2012).
[15] 21 U.S.C. § 321(n) (2012); 21 C.F.R. §§ 1.21, 202.1(e)(5)(iii) (2012).

by the manufacturer] would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.[16]

74. These reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession.

75. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event.[17]

76. Manufacturers are required to make periodic reports to the FDA regarding cleared devices, such reports to include summaries of:

a. Unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant; and,

b. Reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant.[18]

77. The medical device manufacturer has a continuing duty to monitor the product after FDA clearance and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product.

78. The manufacturer is obligated to inform the FDA of new clinical investigations or scientific studies concerning the device about which the manufacturer knows or reasonably should know.[19]

[16] 21 C.F.R. § 803.50(a) (2012); 21 U.S.C. § 360i(a) (2012).
[17] 21 C.F.R. § 803.50(b)(3).
[18] 21 C.F.R. § 814.84(b)(2) (2012).
[19] *Id.*

79. The FDA can revoke its clearance based on these post-approval reports.[20]

80. The manufacturer must establish internal procedures for reviewing complaints and adverse event reports.[21] Medical device manufacturers are required by federal regulation to "establish and maintain" an adverse event database.[22] Pursuant to federal regulations, manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken with regard to the adverse event, and whether the remedial action was reported to FDA as a removal or correction of the device.[23]

81. Federal law also mandates that the FDA establish regulations requiring manufacturer of a medical device to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health.[24]

82. Manufacturers must disclose any reportable MDR event or events, including a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health, to the FDA within 5 business days after becoming aware of such event or events.[25]

83. Device manufacturers must report promptly to FDA any device corrections and removals and maintain records of device corrections and removals.

84. FDA regulations require submission of a written report within ten (10) working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of the Act caused by the device, which may present a risk to health. The written submission must contain, among other things, a description

[20] 21 U.S.C. §§ 360(e)(1), 360(h)(e) (2012).
[21] 21 C.F.R. § 820.198(a) (2012).
[22] 21 C.F.R. § 803.1(a) (2012).
[23] 21 C.F.R. § 803.52 (2012).
[24] 21 U.S.C. § 360(i).
[25] See 21 C.F.R. § 806 (2012).

of the event giving rise to the information reported, the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal and provide a copy of all communications regarding the correction or removal.[26]

85. Pursuant to federal regulation, manufacturers must comply with specific quality system requirements promulgated by FDA. These regulations require manufacturers to meet design control requirements, including but not limited to conducting design validation to ensure that devices conform to defined user needs and intended uses.

86. Manufacturers must also meet quality standards in manufacture and production of the devices.

87. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions; investigate the cause of nonconforming products; and, take corrective action to prevent recurrence.

88. Manufacturers are also required to review and evaluate all complaints and determine whether an investigation is necessary.

89. Manufacturers are also required to use statistical techniques, where necessary, to evaluate product performance.

90. Zimmer failed to comply with several of these requirements which led to the devices being on the market for use by Plaintiff's doctor.

91. Zimmer failed to comply with many of these above-mentioned FDA regulations and requirements.

[26] See 21 C.F.R. § 806 (2012).

92. Zimmer failed to report adverse events timely to the FDA.

93. Zimmer failed to investigate and correct problems with the VerSys Hip System.

C. After Clearance of a Medical Device, The FDA, By Its Regulations and PMA Process, Requires A Manufacturer To Follow Good Manufacturing Practices

94. Under 21 C.F.R. § 820.1(a) (2012) of the Quality System (QS) Regulation for Medical Devices, current good manufacturing practice (CGMP) requirements are set forth in this quality system regulation. The requirements in this part govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements in this part are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (FDCA). This part establishes basic requirements applicable to manufacturers of finished medical devices.

95. 21 C.F.R. § 820.5 (2012) "Quality Systems," the FDA regulations state, "Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part."

96. 21 C.F.R. § 820.3(z)(2) (2012) "Design validation," means the manufacturer must establish objective evidence that device specifications conform with user needs and intended use(s)."

97. 21 C.F.R. § 820.22 (2012): "Quality Audit" states: "Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system."

98. 21 C.F.R. § 820.160(a) (2012): "Distribution" states: "Each manufacturer shall establish and maintain procedures for control and distribution of finished devices to ensure that

only those devices approved for release are distributed and that purchase orders are reviewed to ensure that ambiguities and errors are resolved before devices are released for distribution."

99. 21 C.F.R. § 820.170(a) (2012): "Installation" states: "Each manufacturer of a device requiring installation shall establish and maintain adequate installation and inspection instructions, and where appropriate test procedures. Instructions and procedures shall include directions for ensuring proper installation so that the device will perform as intended after installation. The manufacturer shall distribute the instructions and procedures with the device or otherwise make them available to the person(s) installing the device."

100. 21 C.F.R. § 803 (2012), states: "Manufacturers must include information that is reasonably known to the manufacturer, timely make Medical Device Reporting ("MDR") submissions, define the procedures for implementing corrective and preventative actions, and review sampling methods for adequacy of their intended use."

101. 21 C.F.R. § 820.100 (2012) "Corrective and Preventive Action" states: (a) [e]ach manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

a. Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;

b. Investigating the cause of nonconformities relating to product, processes, and the quality system;

c. Identifying the actions needed to correct and prevent recurrence of nonconforming product and other quality problems;

d. Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device; an

e. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems.

D. Zimmer's Conduct in Violation of the FDCA

102. Zimmer violated these FDCA statutes and accompanying regulations by:

a. falsely and misleadingly promoting the VerSys Hip System;

b. failing to report adverse events to the FDA;

c. failing to timely conduct failure investigations and analysis;

d. failing to timely report any and all information concerning product failures and corrections;

e. failing to timely and fully inform FDA of unanticipated adverse effects, including device corrosion, increases in the incidence of adverse effects, and device failures necessitating a labeling, manufacturing or device modification;

f. failing to conduct necessary design validation;

g. selling and distributing a misbranded and adulterated product through interstate commerce; and

h. failing to immediately disclose the metallosis risk from the fretting and corroding failure of the VerSys Hip System after implantation in patients.

103. Zimmer's violation of these FDCA statutes and accompany regulations, as discussed above, constitutes violation of the state law tort causes of action alleged in this Complaint, as set forth herein.

104. Zimmer's violation of the FDCA statutes and accompany regulations, as discussed above, directly caused or significantly contributed to the use of the VerSys Hip System in Plaintiff and Zimmer's misconduct in this regard thus directly caused or contributed to Plaintiff's injuries and damages.

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION
STRICT LIABILITY - MANUFACTURING DEFECT

106. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

107. Prior to, on, and after the dates of Plaintiff's initial hip surgery, and at all times relevant this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the VerSys Hip System for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

108. The VerSys Hip System was "defective" and "unreasonably dangerous" when it entered the stream of commerce and was received by Plaintiff, because the risks were outweighed by any utility of the design of the device and because the device was dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that the VerSys Hip System was in a condition not suitable for its proper and intended use.

109. At all times herein mentioned, the Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the VerSys Hip System, which was implanted in Plaintiff, such that it was dangerous, unsafe, and defective in manufacture. The defects in manufacture include but are not limited to the following respects:

a. that the VerSys Hip System has the propensity to undergo fretting and corrosion at the femoral head-stem taper juncture causing serious complications in patients;

b. that the VerSys Hip System differed from the manufacturer's intended design or specifications, or from other typical units of the same product line;

c. that the Defendants failed to conduct adequate mechanical testing, including corrosion fatigue or other wear testing, on components, subassemblies and/or the finished VerSys Hip System;

d. that Defendants failed to test an adequate number of sample devices on an ongoing basis;

e. that Defendants failed to take adequate steps to specifically identify failure modes with clarity and to suggest methods to monitor, avoid, and/or prevent further failures;

f. that Defendants failed to identify and/or note the significance of any testing that resulted in failure of the VerSys Hip System;

g. that Defendants failed to take corrective actions to eliminate or minimize further failures of the VerSys Hip System;

h. that Defendants failed to adequately explain performance specifications for the components, subassemblies, and/or the finished VerSys Hip System;

i. that Defendants failed to adequately explain or justify all test conditions and acceptance criteria for the VerSys Hip System;

j. that Defendants failed to perform adequate testing in an environment that adequately simulated in vivo conditions;

k. that Defendants failed to perform adequate testing of the VerSys Hip System, including its components and subassemblies, to ensure that the VerSys Hip System functioned properly during and after implantation; and

l. that Defendants failed to perform adequate quality assurance testing and validation before and after sterilization.

110. Plaintiff's physicians employed the VerSys Hip System in the manner in which it was intended and recommended to be used, making such use reasonably foreseeable to Defendants.

111. The VerSys Hip System as tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold by Defendants reached Plaintiff without substantial change in its condition.

112. As alleged herein, Defendants knew and had reason to know that the VerSys Hip System caused an increased risk of harm to the Plaintiff and other consumers due to the device's greater propensity to undergo significant fretting and/or mechanically assisted crevice corrosion at the femoral head-stem taper juncture resulting in elevated serum metal ion levels, adverse local tissue reactions, pseudotumor formation, tissue destruction, metallosis, and the need for revision surgery.

113. Defendants consciously disregarded this increased risk of harm by failing to warn of such risks; unlawfully concealing the dangerous problems associated with implantation of the VerSys Hip System; and continuing to market, promote, sell and defend the device.

114. As alleged herein, the defects in manufacture of the VerSys Hip System were a substantial factor in causing Plaintiffs' injuries.

115. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including the defective manufacture of the VerSys Hip System, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening, impingement and/or detachment; metallosis; soft tissue damage; adverse local tissue reaction; dislocation; infection; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of the defective nature of the VerSys Hip System, Plaintiff has sustained and will sustain future damages, including but not limited to additional revision surgeries; cost of medical care; rehabilitation; home health care; lost wages; loss of earning capacity; mental and emotional distress; and pain and suffering for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

SECOND CAUSE OF ACTION
STRICT LIABILITY – DESIGN DEFECT

116. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

117. Prior to, on, and after the dates of Plaintiff's initial hip surgery, and at all times relevant to this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the VerSys

Hip System for implantation into consumers, such as Plaintiff, by physicians and orthopedic surgeons in the United States.

118. The VerSys Hip System was defective in design and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff, because the risks were outweighed by any utility of the design of the device and because the device was dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that the VerSys Hip System was in a condition not suitable for its proper and intended use.

119. The VerSys Hip System was defective in design and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff, because the foreseeable risks exceeded or outweighed the purported benefits associated with the device.

120. At all times relevant to this action, the Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the VerSys Hip System, which was implanted in Plaintiff, such that it was dangerous, unsafe, and defective in design.

121. The VerSys Hip System implanted in Plaintiff was defective in design in all or some of, and without limitation, the following respects:

a. The device employs a femoral stem-head taper junction which due to its taper size and geometry, the use of dissimilar metal alloys, trunnion surface finish, and rigidity and has the propensity to undergo fretting and/or mechanically assisted crevice corrosion at the femoral head-stem taper junction causing serious complications in patients;

b. The device employs a femoral head which by virtue of its taper size, taper angle and taper geometry has the propensity to undergo fretting and/or mechanically assisted crevice corrosion at the femoral head-stem taper junction causing serious complications in patients; and

c. The device employs a femoral stem which by virtue of its taper size, taper angle, material, surface area, and rigidity has the propensity to undergo fretting and/or mechanically assisted crevice corrosion at the femoral head-stem taper junction causing serious complications in patients.

122. Plaintiff's physicians employed the VerSys Hip System in the manner in which it was intended to be used, making such use reasonably foreseeable to Defendants.

123. The VerSys Hip System as tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold by Defendants reached Plaintiff without substantial change in its condition.

124. As alleged herein, Defendants knew and had reason to know that the VerSys Hip System caused an increased risk of harm to the Plaintiff and other consumers due to the device's greater propensity to undergo significant fretting and/or mechanically assisted crevice corrosion at the femoral head-stem taper junction resulting in elevated serum metal ion levels, adverse local tissue reactions, pseudotumor formation, tissue destruction, metallosis, and the need for revision surgery. Defendants consciously disregarded this increased risk of harm by failing to adequately warn of the risk; unlawfully concealing the dangerous problems associated with implantation of the VerSys Hip System; and continuing to market, promote, sell and defend the VerSys Hip System.

125. As alleged herein, the defects in design of the VerSys Hip System were a substantial

factor in causing Plaintiff's injuries.

126. Defendants failed to develop and make available alternative products that were designed in a safe or safer manner, even though such products were feasible and marketable and, in fact, were being sold and marketed by Defendants at the time Defendants sold the VerSys Hip System to Plaintiff.

127. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including the defective design of the VerSys Hip System, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening, impingement and/or detachment; metallosis; soft tissue damage; adverse local tissue reaction; dislocation; infection; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of the defective nature of the VerSys Hip System, Plaintiff has sustained and will sustain future damages, including but not limited to additional revision surgeries; cost of medical care; rehabilitation; home health care; lost wages; loss of earning capacity; mental and emotional distress; and pain and suffering for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

THIRD CAUSE OF ACTION
STRICT LIABILITY – FAILURE TO WARN

128. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

129. Prior to, on, and after the dates of Plaintiff's initial hip surgery, and at all times relevant to this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the VerSys Hip System for implantation into consumers, such as Plaintiff, by physicians and orthopedic

surgeons in the United States.

130. The VerSys Hip System was defective and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff, because the risks were outweighed by any utility of the design of the device and because the device was dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that the VerSys Hip System was in a condition not suitable for its proper and intended use.

131. The VerSys Hip System was defective in design and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff, because the foreseeable risks exceeded or outweighed the purported benefits associated with the device.

132. The VerSys Hip System posed increased risks of harm and side effects that were known or knowable to Defendants by the use of scientific knowledge available before, at and after the time of manufacture, distribution, and sale of the VerSys Hip System to Plaintiff.

133. Defendants knew or should have known of the defective condition, dangerous characteristics, and risks associated with the VerSys Hip System as alleged herein.

134. Defendants consciously disregarded the increased risks of harm by failing to adequately warn of such risks; unlawfully concealing the dangerous problems associated with implantation of the VerSys Hip System; and continuing to market, promote, sell and defend the VerSys Hip System.

135. The VerSys Hip System that was manufactured, distributed, and sold by the Defendants to Plaintiff was in a defective condition that was unreasonably dangerous to any user or ordinary consumer of the device, including Plaintiff.

136. Such ordinary consumers, including Plaintiff, would not and could not have recognized or discovered the potential risks and side effects of the VerSys Hip System as alleged herein.

137. The instructions for use, directions and warnings provided by Defendants with the VerSys Hip System failed to adequately convey the potential risks and side effects of the VerSys Hip System and the dangerous propensities of the device, which risks were known or were

reasonably scientifically knowable to Defendants. In particular, Defendants failed to adequately disclose the greater propensity of the VerSys Hip System to undergo significant fretting and/or mechanically assisted crevice corrosion at the femoral head-stem taper junction.

138. The VerSys Hip System was expected to and did reach Plaintiff and her orthopedic surgeon without substantial change in its condition as manufactured, distributed, and sold by Defendants.

139. Plaintiff's orthopedic surgeon used the VerSys Hip System in the manner in which it was intended to be used, making such use reasonably foreseeable to Defendants.

140. The lack of adequate instructions for use, directions and warnings with the VerSys Hip System prior to, on, and after the dates of Plaintiff's initial hip surgery were a substantial factor in causing Plaintiff's injuries, losses and damages as alleged herein.

141. Defendants failed to develop and make available alternative products that were designed in a safe or safer manner, even though such products were feasible and marketable and, in fact, were being sold and marketed by Defendants at the time Defendants sold the VerSys Hip System to Plaintiff.

142. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants' lack of sufficient instructions or warnings, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening, impingement and/or detachment; metallosis; soft tissue damage; adverse local tissue reaction; dislocation; infection; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of the defective nature of the VerSys Hip System, Plaintiff has sustained and will sustain future damages, including but not limited to additional revision surgeries; cost of medical care; rehabilitation; home health care; lost wages; loss of earning capacity; mental and emotional distress; and pain and suffering for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

FOURTH CAUSE OF ACTION
NEGLIGENCE – DESIGN, MANUFACTURE & SALE

143. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

144. Prior to, on, and after the dates of Plaintiff's initial hip surgery, and at all times relevant to this action, Defendants had a duty to exercise reasonable care in testing, study, research, design, formulation, manufacture, inspection, labeling, packaging, promotion, advertisement, marketing, distribution and sale of the VerSys Hip System for implantation into consumers, such as Plaintiff, by physicians and surgeons in the United States.

145. Prior to, on, and after the dates of Plaintiff's initial hip surgery, Defendants failed to exercise reasonable care and were negligent and careless in the testing, study, research, design, formulation, manufacture, inspection, labeling, packaging, promotion, advertisement, marketing, distribution and sale of the VerSys Hip System.

146. Prior to, on, and after the dates of Plaintiff's initial hip surgery, Defendants failed to perform adequate evaluation and testing of the VerSys Hip System, where such adequate evaluation and testing would have revealed the device's propensity to undergo fretting and mechanically assisted crevice corrosion at the femoral head-stem taper junction causing serious complications in patients.

147. Prior to, on, and after the dates of Plaintiff's initial hip surgery, Defendants had received complaints from healthcare providers that the VerSys Hip System caused serious complications including but not limited to fretting and mechanically assisted crevice corrosion at the femoral head-stem taper junction, but Defendants nonetheless consciously decided not to perform any further testing on the VerSys Hip System; investigate the root cause of these complications; suspend sales and distribution of the device; or warn physicians and patients of the propensity of the VerSys Hip System to undergo fretting and/or mechanically assisted crevice corrosion at the femoral head-stem taper junction causing serious complications in patients.

148. Defendants' failure to exercise reasonable care in the design, testing, distribution,

manufacture, advertising, sales, and marketing prior to, on, and after the dates of Plaintiff's initial hip surgery was a substantial factor in causing Plaintiffs' injuries, losses, and damages, as alleged herein.

149. As alleged herein, Defendants knew and had reason to know that the VerSys Hip System caused increased risk of harm to Plaintiff and other consumers. Defendants consciously disregarded this increased risk of harm by failing to warn of such risks; unlawfully concealing the dangerous problems associated with implantation of the VerSys Hip System; and continuing to market, promote, sell and defend the VerSys Hip System.

150. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants' failure to exercise reasonable care as described herein, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening, impingement and/or detachment; metallosis; soft tissue damage; adverse local tissue reaction; dislocation; infection; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of the defective nature of the VerSys Hip System, Plaintiff has sustained and will sustain future damages, including but not limited to additional revision surgeries; cost of medical care; rehabilitation; home health care; lost wages; loss of earning capacity; mental and emotional distress; and pain and suffering for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

FIFTH CAUSE OF ACTION
NEGLIGENCE – FAILURE TO WARN

151. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

152. Prior to, on, and after the dates of Plaintiff's initial hip surgery, and at all relevant times, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the VerSys Hip System

for implantation into consumers, such as Plaintiff, by physicians and orthopedic surgeons in the United States.

153. Prior to, on, and after the dates of Plaintiff's initial hip surgery, Defendants knew or should have known that the VerSys Hip System was dangerous or was likely to be dangerous when used in a reasonably foreseeable manner. Such danger included the propensity of the VerSys Hip System's to undergo fretting and/or mechanically assisted crevice corrosion at the femoral head-stem taper junction causing serious complications in patients.

154. Prior to, on, and after the dates of Plaintiff's initial hip surgery, Defendants knew or reasonably should have known that the users of the device, including Plaintiff, would not realize the dangers presented by the device.

155. Prior to, on, and after the dates of Plaintiff's initial hip surgery, Defendants failed to adequately warn of the dangers presented by the device and/or failed to instruct on the safe use of the device. Such failures to warn and/or instruct included, but were not limited to failing to advise of the known or knowable risks, dangers, and side effects associated with the use of the VerSys Hip System; failing to properly advise of the means and methods available for the elimination of the risks, dangers, and side effects associated with the VerSys Hip System; failing to warn physicians about the risks, dangers, and side effects associated with the VerSys Hip System, including the propensity of the VerSys Hip System's to undergo fretting and/or mechanically assisted crevice corrosion at the femoral head-stem taper junction causing serious complications in patients; and failing to warn consumers about the risks, dangers, and side effects associated with the VerSys Hip System, including the propensity of the VerSys Hip System to undergo fretting and/or mechanically assisted crevice corrosion at the femoral head-stem taper junction causing serious complications in patients.

156. Reasonable manufacturers and distributors, under the same or similar circumstances prior to, on, and after the dates of Plaintiff's initial hip surgery, would have adequately warned of the dangers presented by the VerSys Hip System, or provided adequate instructions for the safe use of the VerSys Hip System.

157. Prior to the dates of Plaintiff's initial hip surgery, the VerSys Hip System had already caused numerous known reports of fretting and/or mechanically assisted crevice corrosion at the taper junction between the femoral head and femoral stem. Defendants consciously decided neither to warn physicians or patients of the VerSys Hip System's increased propensity to cause these serious complications, nor of the signs and symptoms of these complications.

158. Defendants' negligent failure to warn Plaintiff, Plaintiff's orthopedic surgeon or Plaintiff's other healthcare providers prior to, on, and after the dates of Plaintiff's initial hip surgery was a substantial factor in causing Plaintiffs' injuries, losses and damages as described herein.

159. As alleged above, Defendants knew and had reason to know that the VerSys Hip System caused an increased risk of harm to Plaintiff and other consumers. Defendants consciously disregarded this increased risk of harm by failing to warn of such risks; unlawfully concealing the dangerous problems associated with implantation of the VerSys Hip System; and continuing to market, promote, sell and defend the VerSys Hip System.

160. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants' negligent failure to warn, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening, impingement and/or detachment; metallosis; soft tissue damage; adverse local tissue reaction; dislocation; infection; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of the defective nature of the VerSys Hip System, Plaintiff has sustained and will sustain future damages, including but not limited to additional revision surgeries; cost of medical care; rehabilitation; home health care; lost wages; loss of earning capacity; mental and emotional distress; and pain and suffering for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

SIXTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES

161. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

162. Defendants impliedly warranted that the VerSys Hip System, which Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold to Plaintiff, was merchantable and fit and safe for ordinary use.

163. Defendants further impliedly warranted that the VerSys Hip System, which Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold, was fit for the particular purposes for which it was intended and was sold.

164. Contrary to these implied warranties, the VerSys Hip System was defective, unmerchantable, and unfit for its ordinary use when sold, and unfit for the particular purpose for which it was sold.

165. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants' breach of implied warranties, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening, impingement and/or detachment; metallosis; soft tissue damage; adverse local tissue reaction; dislocation; infection; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of the defective nature of the VerSys Hip System, Plaintiff has sustained and will sustain future damages, including but not limited to additional revision surgeries; cost of medical care; rehabilitation; home health care; lost wages; loss of earning capacity; mental and emotional distress; and pain and suffering for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

SEVENTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTIES

166. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

167. Defendants expressly warranted to Plaintiff by and through Defendants and/or their authorized agents or sales representatives, in publications, product information, instructions for use, sales and marketing materials, the internet, and other communications intended for physicians, patients, Plaintiff, and the general public, that the VerSys Hip System was safe, effective, fit and proper for its intended use.

168. In allowing the implantation of the VerSys Hip System, Plaintiff and Plaintiff's physicians relied on the skill, judgment, representations, and the express warranties of Defendants.

169. These warranties and representations were false in that the VerSys Hip System was not safe and was unfit for the uses for which it was intended.

170. Through the sale of the VerSys Hip System, Defendants are merchants pursuant to Section 2-314 of the Uniform Commercial Code.

171. Defendants breached their warranty of the mechanical soundness of the VerSys Hip System by continuing sales and marketing campaigns highlighting the safety and efficacy of the device, when Defendants knew of the defects, risk and propensity of the device to undergo fretting and/or mechanically assisted crevice corrosion at the femoral head-stem taper junction causing serious complications in patients.

172. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants' breach of express warranties, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening, impingement and/or detachment; metallosis; soft tissue damage; adverse local tissue reaction; dislocation; infection; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of the defective nature of the VerSys

Hip System, Plaintiff has sustained and will sustain future damages, including but not limited to additional revision surgeries; cost of medical care; rehabilitation; home health care; lost wages; loss of earning capacity; mental and emotional distress; and pain and suffering for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

EIGHTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

173. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

174. At the time Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the VerSys Hip System to Plaintiff, Defendants knew or should have known of the use for which the device was intended and the serious risks and dangers associated with such use of the VerSys Hip System.

175. Defendants owed a duty to orthopedic surgeons, including Plaintiff's implanting physician, Dr. Michaud, and other healthcare providers and to consumers of the VerSys Hip System, including Plaintiff, to accurately and truthfully represent the risks of VerSys Hip System.

176. Defendants breached their duty by misrepresenting and/or failing to adequately warn Plaintiff's orthopedic surgeon, the medical community, Plaintiff, and the public about the risks of the VerSys Hip System, including the device's greater propensity to undergo significant fretting and/or mechanically assisted crevice corrosion at the femoral head-stem taper junction, which Defendants knew or in the exercise of diligence should have known.

177. Among Defendants' numerous misrepresentations and misleading omissions are Defendants' assurances that the VerSys Hip System was safe, had an excellent performance record, and did not have a greater propensity or risk to undergo significant fretting and/or mechanically assisted crevice corrosion. Instead, Defendants stated or implied to orthopedic surgeons, patients

and the FDA that any problem with the VerSys Hip System in a particular patient was attributable to "surgical technique" or patient factors such as body mass index, bone composition, and post-implantation activity level. Defendants made such statements even after they became aware of numerous and serious complications with the VerSys Hip System. Defendants did not reveal (and instead concealed) their knowledge of numerous and serious complications and other bad data during their meetings with orthopedic surgeons and the FDA.

178. Despite their knowledge of serious problems with the VerSys Hip System, Defendants, by their Executives, Directors, and Staff, an urged their sales representatives to continue marketing the VerSys Hip System, and distributed medical literature and other communications to surgeons, including Dr. Michaud, in an effort to mislead them and the general public about the risks associated with the VerSys Hip System and instead create the image and impression that the VerSys Hip System was safe.

179. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants' negligent misrepresentations, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening, impingement and/or detachment; metallosis; soft tissue damage; adverse local tissue reaction; dislocation; infection; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of the defective nature of the VerSys Hip System, Plaintiff has sustained and will sustain future damages, including but not limited to additional revision surgeries; cost of medical care; rehabilitation; home health care; lost wages; loss of earning capacity; mental and emotional distress; and pain and suffering for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

NINTH CAUSE OF ACTION
VIOLATION OF VIRGINIA'S UNFAIR TRADE PRACTICES ACT
(Va. Code Ann. § 38.2-500-518)

180. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

181. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion, and/or sale of the VerSys Hip System.

182. Had the Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for the VerSys Hip System and would not have incurred related medical costs.

183. Specifically, Plaintiff and Plaintiff's physicians were misled by the deceptive conduct as described herein.

184. Defendants' deceptive, unconscionable, and/or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of Va. Code Ann. § 38.2-500-518.

185. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, substantial sums of money from Plaintiff for the VerSys Hip System that Plaintiff would not have paid had Defendants not engaged in unfair and deceptive conduct.

186. Defendants' actions, as alleged herein, constitute unfair competition or unfair, unconscionable, deceptive, and/or fraudulent acts or trade practices in violation of Va. Code Ann. § 38.2-500-518.

187. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create a demand for and sell the VerSys Hip System. Each aspect of Defendants' conduct combined to artificially create sales of the VerSys Hip System.

188. The medical community relied upon Defendants' misrepresentations and omissions in determining which hip implant to utilize for a patient.

189. By reason of the unlawful acts engaged in by Defendants, Plaintiff has suffered ascertainable loss and damages.

190. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff was damaged by paying in whole or in part for the VerSys Hip System. As a direct and proximate result of Defendants' violations of Va. Code Ann. § 38.2-500-518., Plaintiff has sustained economic losses and other damages for which Plaintiff is entitled to statutory and compensatory damages, and declaratory relief, in an amount to be proven at trial.

CONDITIONS PRECEDENT

191. All conditions precedent to Plaintiffs' right to recover herein and to Defendants' liability have been performed or have occurred.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, as follows:

1. Compensatory damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for Plaintiff's injuries and damages, both past and present;

2. Special damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all of Plaintiff's injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, lost income or wages, loss of earning capacity, permanent disability, including permanent instability and loss of balance, pain and suffering, and loss of consortium;

3. Punitive damages as allowed by law;

4. Double or triple damages as allowed by law;

5. Attorneys' fees, expenses, and costs of this action;

6. Pre-judgment and post-judgment interest in the maximum amount allowed by law; and

7. Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiff demands a trial by jury of all claims asserted in this Complaint.

Dated: May 15, 2019

Respectfully submitted,

/s/ Jonathan A. Hogins

Jonathan A. Hogins, VA Bar No. 83982
THE MOODY LAW FIRM
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